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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,429	10/20/1999	TOSHIHIRO SHIMIZU	2535USOP	7265

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	37

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Applicati n No. 09/403,429	Applicant(s) SHIMIZU ET AL.	
	Examiner Susan Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,21,23-26 and 28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21,23-26 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *35* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Request for The Extension of Time, Request for Continued Examination under 37 CFR 1.114, Information Disclosure Statement, and Preliminary Amendment filed 04/03/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/03/03 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20, 21, 23-26, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. US 6,299,904.

Shimizu teaches a buccal disintegration formulation comprising low-substituted hydroxypropylcellulose (7.0-9.9 %), sugar, and active agent, such as lansoprazole

(columns 1-3). The dissolution time of the buccal formulation is from about 5 to about 50 seconds (column 8, lines 1-5). Although Shimizu teaches lansoprazole among many other active agents may be used, it is the position of the examiner that it would have been obvious for the skilled artisan to, by routine experimentation obtain the claimed invention, because Shimizu specifically teaches the use lansoprazole in example 5. The expected result would be a storage stable of quick dissolved formulation of lansoprazole, which can be orally administered without water.

The examiner notes that Shimizu is silent as to the teaching of tablet having improved chalky taste and no roughness as claimed in claims 30 and 32. However, "when the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977); or products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." Therefore, it is the position of the examiner that Shimizu's tablet would have similar result because Shimizu teaches the use of similar low-substituted hydroxypropylcellulose.

Claims 20, 21, 23-26, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al. US 5,958,453, in view of Shimizu et al. US 6,299,904.

Ohno teaches improved buccal disintegrability formulation comprising active agent, mannitol or erythritol, cellulose, e.g., low-substituted hydroxypropyl cellulose (columns 2-5). The formulation can be compressed into tablet that has dissolution time of about 0.1 to 1.0 minute (column 6, lines 65-67).

Ohno does not expressly teach the claimed active agent, *e.g.*, lansoprazole.

Shimizu teaches a buccal disintegration formulation comprising low-substituted hydroxypropylcellulose (7.0-9.9 %), sugar, and active agent, such as lansoprazole (columns 1-3). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Ohno's formulation using lansoprazole as an active agent in view of the teaching of Shimizu. The reason for this modification is to obtain a buccal disintegrable solid dosage useful for the treatment of the digestive diseases.

Although Ohno is silent as to the teaching of the degree substituted of the hydroxypropyl group, Ohno recognizes the advantages result in obtaining buccal tablet having dissolution time within the claimed range. However, it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation select a suitable low-substituted hydroxypropyl cellulose to obtain a rapid disintegrate buccal tablet. The expected result would be a buccal dissolution dosage that has long shelf-life, low toxicity, ease of administration even without water, and having fast disintegration in the oral cavity even without water (column 7, lines 3-25).

Claims 20, 21, 23-26, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al. US 5,958,453, in view of Shashoua et al. US 6,299,904.

Ohno is relied upon for the reasons stated above. Ohno is silent as to the specific active agent claimed by the applicant, e.g., lansoprazole.

Shashoua teaches pharmaceutical composition in tablet form comprising active ingredients, e.g., lansoprazole (column 35, lines 4-10). The composition further comprising pharmaceutically acceptable carrier (column 48, lines 22-32). Thus, it would have been obvious for one of ordinary skill in the art to modify Ohno's formulation using lansoprazole as an active agent in view of the teaching of Shashoua. The reason for this modification is to obtain a buccal disintegrable solid dosage useful for the treatment of the digestive diseases. The expected result would be a storage stable quick dissolve buccal formulation that can be safely administered orally without water.

Response to Arguments

Applicant's arguments filed 04/03/03 have been fully considered but they are not persuasive.

Applicant indicated that a Certified Copy of the translation of the Japanese priority document with their last response, to ensure that priority had been perfected fro the present application, therefore, the Shimizu reference is not a proper prior art and the rejection should be withdrawn. Unfortunately, the examiner neglected to address this point in the latest Office Action. Applicant's Certified Copy of the translation of the Japanese Patent Application No. 213049-1998 is acknowledged. However, as

disclosed on page 3 of the Office Action (paper No. 26, dated 04/12/02), the examiner indicated that "the examiner relies on the foreign priority date of the Shimizu reference until a translation of said foreign priority is provided/obtained, the patentability will be reconsidered". ***The examiner acknowledges the priority date of the instant application is filed on 07/28/1998; however, applicant's attention is drawn to the priority date of the Shimizu reference, which is filed on 05/27/1997. A Certified Copy of the translation of the Shimizu reference's foreign priority document (Japanese Patent Application On. 9-136724) is provided herein for applicant's convenience. Accordingly, the Shimizu reference is qualified as a prior art.***

Applicant argues the rejection using reference '357 is confusing. According to the office action, there was no reference '357. Further clarification is requested.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wantanabe et al. is cited as being of interest for the teaching of rapidly disintegrate compressed tablet.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600